

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gary De Jong, et al.
Serial No. : 09/815,979
Filed : March 22, 2001
Confirmation No.: 7635
Title : METHODS FOR DELIVERING NUCLEIC ACID MOLECULES INTO CELLS AND ASSESSMENT THEREOF

Art Unit : 1636
Examiner : Daniel M. Sullivan
Customer No.: 20985

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER


Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement, Form PTO-1449, cited references, return postcard, and a check for the requisite fee of \$180.00 for filing in connection with the above-captioned patent application.



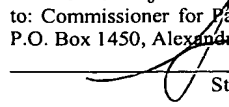
The Commissioner is hereby authorized to charge the fee for the extension of time and any other fee that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,


Stephanie L. Seidman
Reg. No. 33,779

Attorney Docket No. 17084-018001/24601-416
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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.


Stephanie L. Seidman



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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Since this Supplemental Information Disclosure Statement is filed after the receipt of a first Office Action on the merits for the above-captioned application, the filing fee of \$180.00 is enclosed. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account no. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§ 1.97-1.98. Form PTO-1449 (1 page) and copies of the cited documents are provided herewith.

The cited documents, listed on Form PTO-1449 and supplied herewith, are in the English language. Hence, in accordance with the requirements of 37 C.F.R. § 1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

The Examiner's attention is directed to the reference Oberle *et al.* (*Biochimica et Biophysica Acta* (2004) 1676:223-230), accompanying the Supplemental Information Disclosure Statement filed April 2, 2004 (Item AD), in connection with the above-captioned application. Oberle *et al.* describes methods for delivering artificial chromosome expression systems (ACEs) to cells. Specifically, Oberle *et al.* demonstrates that when cells are treated

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I hereby certify that this paper and the attached papers are being deposited with the United States Postal Services as "Express Mail" Label No. EV 399295641 US in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

June 21, 2004

Stephanie L. Seidman

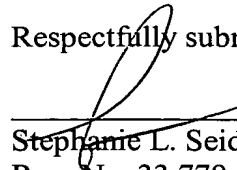
with ultrasound energy and the cationic lipid SAINT-2 or DOTAP prior to contacting cells with ACEs, the ACEs are delivered into the cells. Oberle *et al.* states that incubation of ACEs with cationic lipids such as SAINT-2 and DOTAP to prepare ACEs/lipid complexes leads to partial unraveling of the ACEs with a loss of their condensed structure (*see* page 225, col. 1, para. 2). Oberle *et al.* does not provide any data to support this statement.

The instant application describes complexation of ACEs with delivery agents such as cationic lipids to facilitate introduction of the ACEs into cells (*see, e.g.*, Examples 4-7). The instant application demonstrates that ACEs that are complexed with delivery agents such as cationic lipids can maintain their intact and condensed structure before and after delivery into the cells (*see, e.g.*, aforementioned Examples; *see also* de Jong *et al. Chromosome Res.* (2001) 9:475-485 and Vanderbyl *et al. Cytometry* (2001) 44:100-105, which are of record in this application).

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. § 1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing references and information and that they be made of record in the file history of the above-captioned application.

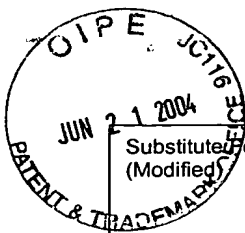
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17084-018001 (24601-416)	Application No. 09/815,979
List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b))		Applicant Gary De Jong, et al.	
		Filing Date March 22, 2001	Group Art Unit 1636

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,747,338	05/05/98	Giese et al.	435	348	09/25/96

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AB	Compton et al., "An improved method for routine preparation of intact artificial chromosome DNA (340-1000kb) for transfection into human cells," <i>Nucleic Acids Research</i> 27(7):1762-5 (1999)
	AC	Mascarenhas et al., "Gen Delivery to Human B-Precursor Acute Lymphoblastic Leukemia Cells," <i>Blood</i> 92(10):3537-3545 (1998)
	AD	Oberle et al., "Efficient transfer of chromosome-based DNA constructs into mammalian cells," <i>Biochimica et Biophysica Acta</i> 1676:223-230 (2004)
	AE	Asahara et al., "Stem cell therapy and gene transfer for regeneration", <i>Gene Therapy</i> , 7:451-457 (2000)
	AF	Isner, J.M. et al. "Angiogenesis and vasculogenesis as therapeutic strategies for postnatal neovascularization", <i>J. Clinical Investigation</i> 103(9): 1231-1236 (1999)
	AG	Springer et al., "VEGF Gene Delivery to Muscle: Potential role for Vasculogenesis in Adults", <i>Molecular Cell</i> , 2:549-558 (1998)
	AH	Yoo et al., "Chondrogenitor Cells and Gene Therapy", <i>Clinical Orthopaedics and Related Research</i> , 379S:S164-S170 (2000)

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	